REMARKS/ARGUMENTS

Rejection of Claims 1, 4, and 11-16 Under 35 U.S.C. 102(b) / 35 U.S.C. 103(a)

Claims 1, 4, and 11-16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fearnot et al. (US 5609629). Applicant respectfully disagrees with the Examiner's rejection.

Fearnot is directed towards developing reliable devices and methods for delivering agents to a body. Specifically, Fearnot teaches an implantable medical device (e.g. a stent) composed of a base material, with at least one layer of a bioactive material positioned over the structure, and at least one porous layer positioned over the bioactive material layer. The at least one porous layer has a thickness adequate to provide a controlled release of the bioactive material. Fearnot also discloses variations wherein additional layers of bioactive material and porous layers are provided.

Claim 1 of the instant application reads as follows:

1. A stent, comprising:

a material having structure to provide visualization of a surrounding tissue when said stent is inserted into said tissue and viewed under an imaging beam,

said stent having (i) a coating selected from a group consisting of: (i)(a) a hydrophilic polymer, (i)(b) a hydrophobic polymer, and (i)(c) a fatty acid polymer, and (ii) a density enhancing radiologic opacifier material embedded into said polymer,

said coating and said embedded opacifier material together providing a first Hounsfield image density suitable for viewing under a first image modality used during device insertion into a patient, and wherein

said density enhancing radiologic opacifier material is configured to elute from said coating so as to provide a second Hounsfield image density suitable for viewing under a second image modality used for subsequent 3-D visualization of surrounding tissue.

The Applicant respectfully submits that Fearnot fails to teach or suggest a device having an elutable radiologic opacifier material for the purpose of obtaining two different Hounsfield image densities, where each of the different image densities is suitable for imaging under different imaging modalities. While Fearnot does make reference to radiopaque agents, and the coating of structures when manufactured of radiolucent material, there is no discussion whatsoever of the elution being configured to provide two differing Hounsfield image densities for imaging under two different imaging modalities. In fact, Fearnot fails to even mention Hounsfield image densities at all.

The Examiner asserts that it is clearly recognized that when radiologic opacifier material in the soluble bioactive polymer dissolves, the radiologic profile of stent 12 will be less pronounce and the morphology of the surrounding tissue will be seen more clearly. Applicant submits that such recognition can only come as a result of hindsight analysis, as Fearnot fails to disclose key features of the invention. The intention in Fearnot was not to obtain the aforementioned dual imaging modality functionality, but rather "to develop devices and methods for reliably delivering suitable agents, drugs or bioactive materials directly into a body portion during or following a medical procedure, so as to treat or prevent such conditions and diseases, for example, to prevent abrupt closure and/or restenosis of a body portion such as a passage, lumen or blood vessel [Fearnot, Col 2, ln 38-43]. Clearly, the primary thrust behind Fearnot is the reliable *delivery* of agents, drugs and bioactive materials. Fearnot is not at all concerned with, and fails to teach or suggest, changes in image densities, and in particular the

use of more than one imaging modality, where the change in image density governs the ability to use more than one imaging modality.

Furthermore, Fearnot discloses that "a wide range of other bioactive materials can be employed, including ... radiotherapeutic agents, radiopaque agents and radiolabelled agents." [Fearnot, Col 3, ln 35-43].

One skilled in the art recognizes that these materials, particularly the radiopaque agents, are for use as radiocontrast agents during various medical imaging procedures. Such use requires the agents to permeate into the tissue for imaging, hence their inclusion in the long listing of "bioactive agents." This is analogous to the permeation of drugs from the device into the surrounding tissue for treatment. Fearnot does not contemplate, and fails to teach, the use of an elutable radiopaque agent for the purpose of altering image density of the medical device.

Fearnot further discloses that:

> Of course, when the structure 12 is composed of a radiolucent material such as polypropylene, polyethylene or others above, a conventional radiopaque coating may and preferably should be applied to it. The radiopaque coating provides a means for identifying the location of the structure 12 by X-ray or fluoroscopy during or after its introduction into the patient's vascular system. [Fearnot, Col 7, ln 23-29]

The application of a coating in Fearnot to affect the image density of the structure is accomplished by way of a conventional radiopaque coating, and Fearnot fails to disclose that the conventional radiopaque coating is elutable. Furthermore, Fearnot fails to distinguish between imaging during or after the introduction of the device in the patient, meaning a complete failure to

acknowledge the value in creating a differential in image densities and the resulting ability to use first and second imaging modalities.

It is clear from the above that Fearnot fails to teach or suggest a medical device coated with a coating comprising an opacifier material to provide a first Hounsfield image density suitable for viewing under a first imaging modality, and wherein the opacifier material elutes so as to provide a second Hounsfield image density suitable for viewing under a second image modality.

Notwithstanding the above, claim 1 further distinguishes over Fearnot on the basis that the density enhancing radiologic opacifier material is embedded *into* the polymer. In contrast, Fearnot teaches a construction wherein the bioactive material is deposited as a layer separate from the at least one porous layer:

> "...the present invention is directed to an implantable medical device comprising structure ... the structure being composed of a base material; at least one layer of a bioactive material positioned over the structure; and at least one porous layer positioned over the bioactive material layer ... and being of a thickness adequate to provide a controlled release of the bioactive material." [Fearnot, Col 3, In 17-29]

In fact, Fearnot teaches away from having the bioactive material embedded in the polymer:

> "Careful and precise control over the deposition of the (polymer) permits close control over the release rate of material from the at least one layer of bioactive material. It is for this reason that *the bioactive material lies under the at least one porous layer*, rather than being dispersed within or throughout it." [Fearnot, Col 9, In 53-59]

It is quite clear from the above that the construction taught in Fearnot fundamentally differs from that in the instant application and given that Fearnot

teaches away from embedding the bioactive material into the polymer, one skilled in the art would not have ventured to attempt such a configuration.

In view of the foregoing, Applicant respectfully submits that the claims fully distinguish over Fearnot with respect to both novelty and obviousness. Reconsideration is respectfully requested.

CONCLUSION

Applicant believes that this application is now in condition for allowance. To the extent that any issues remain to be resolved, however, Applicant requests that the Examiner contact the undersigned to resolve these issues.

The Commissioner is also authorized to charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to our Deposit Account No. 50-3750.

Respectfully submitted,

Michael S. Colucci
Reg. No. 58,361
Attorney for Applicant

February 27, 2009

PERRY + CURRIER INC.
1300 Yonge Street
Suite 500
Toronto, Ontario
CANADA, M4T 1X3
Tel.: (416) 920-8170
Fax: (416) 920-1350
Customer No.: 54640